(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 253 353 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
21.03.2012 Bulletin 2012/12

(21) Application number: **10176295.3**

(22) Date of filing: **21.07.2004**

(51) Int Cl.:
A61M 35/00 *(2006.01)* *A61F 13/00* *(2006.01)*

(54) **Negative pressure wound treatment dressing**

Negativdruck-Wundbehandlungskompresse

Pansement de traitement de plaies à pression négative

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PL PT RO SE SI SK TR

(30) Priority: **22.07.2003 US 489344 P**

(43) Date of publication of application:
24.11.2010 Bulletin 2010/47

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
04778864.1 / 1 663 380

(73) Proprietor: **KCI Licensing, Inc.**
San Antonio, TX 78265-9508 (US)

(72) Inventors:
- **Wilkes, Robert**
  San Antonio, TX 78231 (US)
- **Sanders, Teryl Blane**
  San Antonio, TX 78258 (US)

(74) Representative: **Ashton, Timothy**
Forrester & Boehmert
Pettenkoferstrasse 20-22
80336 München (DE)

(56) References cited:
DE-A1- 19 844 355
US-A- 6 135 116
US-A1- 2001 043 943
US-A1- 2002 017 304
US-A1- 2002 082 567

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 2 253 353 B1

Printed by Jouve, 75001 PARIS (FR)

Description

FIELD OF THE INVENTION

[0001] This invention relates to the treatment of open, chronic wounds, as well as burns and skin grafts. More specifically this invention relates to dressings for the treatment of wounds to the extremities, such as the heel of a human foot, by means of negative pressure wound therapy.

BACKGROUND OF THE INVENTION

[0002] Negative pressure wound therapy has been utilized for the treatment of open wounds and has been commercialized by Kinetic Concepts, Inc. of San Antonio, Texas, by its proprietary V.A.C.® product line. In practice, the application to a wound of negative gauge pressure, commercialized by Assignee or its parent under the designation "Vacuum Assisted Closure®" (or "V.A.C.®") therapy, typically involves the mechanical-like contraction of the wound with simultaneous removal of excess fluid, which is often accomplished by means of a polymer foam and occlusive drape dressing in fluid communication with a negative pressure source. In this manner, negative pressure wound therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return. As a result, negative pressure wound therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable.

[0003] Many of these wounds include decubitus and venous stasis ulcers to the lower extremities, especially the foot. Closure of these wounds has been difficult and often times impossible using traditional techniques, such as side grafting, sharp debridement, or combinations thereof. Failure to close these wounds, which have often been present for several years, can lead to necrotizing of the tissue, and in many cases amputation of the extremity. Use of negative pressure wound therapy has proven highly successful in closing these wounds. However, treatment of the lower extremities with negative pressure wound therapy, especially to wounds of the foot and heal can be difficult, especially considering the nature of the location of the wound. Particular concern arises with maintaining the dressing on the extremity, especially in light of the frequent movement of the foot and friction often associated with foot coverings, including socks, stockings, and shoes. Of particular concern, is the ability to maintain a negative pressure at the wound site when the dressing is in place, as air leaks may occur during movement of the foot, which can adversely affect the therapy being administered.

[0004] For the foregoing reasons, there is a need for a negative pressure wound treatment dressing system that is capable of maintaining a negative pressure over an extremity that has heretofore been difficult to treat using traditional negative pressure wound therapy dressings. Additionally, there is a need for a negative pressure wound treatment dressing system that is capable of maintaining a negative pressure over a wound which exists in a highly contoured part of the body, or a portion of the body that undergoes frequent movement or friction against clothing or other outside forces.

[0005] Prior art apparatus are known from the following patent documents. US2001/043943 teaches a wound care bandage for treating a wound. DE19844355 teaches an adhesive wound dressing. US2002/017304 teaches a surgical drape and suction head for wound treatment. Finally, US6135116 teaches a therapeutic apparatus for treating ulcers.

[0006] It is therefore an object of the present invention to provide a negative pressure wound treatment dressing system that provides a means for maintaining a negative pressure over a contoured extremity, such as the foot, and more specifically the heel of the foot.

SUMMARY

[0007] In accordance with the foregoing objects, the present invention generally comprises a contoured porous pad positoned within a fenestrated and contoured occlusive wrapping for placement over a wound on an extremity, such as the heel of a human foot. A concave porous pad is placed adjacent or within the wound, such that the concave pad is enveloped by the occlusive wrapping. Flexible tubing is attached to or through an opening of the drape, so as to allow for fluid communication of negative pressure to the concave pad from a source of negative pressure connected to an opposite end of the flexible tubing. The negative gauge pressure is communicated from the source, through the tube, through the fenestrations of the occlusive wrapping, such that negative gauge pressure is applied to the wound on the extremity. The contoured porous pad serves to manifold the negative pressure from a position away from the wound site to the concave paid at the wound site. Such an arrangement allows for the tubing to connect to the dressing of the present invention at a position least likely to be dislodged during normal ambulation of the patient.

[0008] Attachments means are formed on the outer edges of the occlusive wrapping to form an airtight seal over the wound. Such attachment means may be an adhesive coated on the occlusive wrapping for attachment to an intact area of tissue or skin. The adhesive is coated on the perimeter edge of the occlusive wrapping such that a pouch is formed when the occlusive wrapping is secured over the concave pad.

[0009] A collection canister is provided between the negative pressure source and the occlusive drape for collecting any effluents that may be drawn from the wound during application of negative pressure.

[0010] The tubing is connected to the drape and pad through an opening in the drape, or through a flanged

tubing connector as has been described in U.S. Patent 6,345,623, entitled "Surgical drape and suction head for wound treatment," to Heaton, et al. Alternative embodiments allow the tubing to be placed within or embedded in the concave padding.

[0011] The foregoing has outlined some of the more pertinent objects of the present invention. These objects should be construed to be merely illustrative of some of the more prominent features and application of the invention. Many other beneficial results can be attained by applying the disclosed invention in a different manner or by modifying the invention as will be described. Accordingly, other objects and a fuller understanding of the invention may be had by referring to the following Detailed Description of the Invention, which includes the preferred embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] These and other features and advantages of the invention will now be described with reference to the drawings of certain preferred embodiments, which are intended to illustrate and not to limit the invention, and wherein like reference numbers refer to like components, and in which:

[0013] Figure 1A, is an exploded view of the occlusive wrapping of the present invention.

[0014] Figure 1B, is an orthogonal flat pattern view of the occlusive wrapping of the present invention.

[0015] Figure 2 is an orthogonal view of the fluid manifold of the occlusive wrapping of the present invention.

[0016] Figure 3A is a perspective view of a contoured pad of the present invention.

[0017] Figures 3B and 3C are cross-sectional views of a contoured pad of the present invention.

[0018] Figure 3D is a top plane view of the contoured pad of the present invention.

[0019] Figures 4A-4G are perspective views of the negative pressure wound treatment dressing system, illustrating the steps of applying the dressing system to a wound on the heel of a foot

[0020] Figure 5 is an orthogonal flat pattern view of the occlusive wrapping of the present invention folded along its center line.

DETAILED DESCRIPTION

[0021] Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention as well as alternate embodiments, the scope of which is limited only by the claims that may be drawn hereto.

[0022] The details of the preferred embodiments of present invention are graphically and schematically illustrated in the accompanying drawings. Like elements in the drawings are represented by like numbers, and any similar elements are represented by like numbers with a different lower case suffix:

[0023] Referring now to Figure 1 in particular, there is illustrated the primary components of the occlusive wrapping **10** of the negative pressure dressing system that operates in accordance with the present invention. The occlusive wrapping **10** consists of a fluid manifold **14** embedded within an occlusive drape **16.** The occlusive drape **16** is preferably made of a clear vapor permeable polyurethane material. The drape **16** is composed of a wound facing layer **16a** and an outer layer **16b** that are sealed along their periphery to secure the fluid manifold **14** within the wound facing layer 16a and the outer layer **16b** of the drape **16**. Multiple fenestrations **19** are formed along a wound contact region 17 of the wound facing layer **16a,** so as to allow for fluid communication through the fluid manifold **14.** The fluid manifold **14** allows for attachment of the fluid communication port **18** at a position away from the wound site. The type of wounds desired to be treated by the present system are often situated at a position that has, at times been difficult to maintain a reduced pressure using traditional negative pressure wound therapy techniques described herein. The occlusive wrapping **10** of the present invention overcomes this difficulty by communicating the negative pressure along the manifold **14**, and more particularly the fluid manifold **14** of the occlusive wrapping **10,** which is most clearly illustrated in Figure 2.

[0024] Figure 2 illustrates air alternative embodiment of the fluid manifold **14** of the occlusive wrapping **10**. The fluid communication port **18** is attached to a receiving site **20**, which is most preferably a circular shaped foam section that is approximately the size of the fluid communication port **18.** Fluid communicator arms **22** extend distally from the receiving site **20** to the wound contact regions **17**. The fluid communicator arms **22** terminate in loops **24**, having openings for viewing the wound perimeter. In an alternative embodiment, fluid communicator fingers **24** extend distally from the fluid communicator arms **22.**

[0025] A contoured pad **26** as illustrated in Figures **3A-3D** is utilized as a wound contact screen to prevent unwanted adhesions, direct fluid away from the wound through pores within the pad **26,** and exert contracting forces on the wound margins as negative pressure is applied through the manifold **14** and to the pad **26.** The contoured pad **26** and fluid manifold **14** of the occlusive wrapping **10** are preferably made of a porous polymer foam material, such as polyurethane or polyvinyl alcohol foam. The pad **26** is preferably constructed into an elliptical shape as illustrated in Figure 3D, but may also be more symmetrically circular to accommodate more uniform wounds.

[0026] In practice, the contoured pad **26** is trimmed to the areal dimensions of the wound and is placed in the wound, which may be on the heel of a foot, and between the wound and the fluid manifold **14,** as illustrated in Figures 4A-4G. The pad **26** may be secured to the wound

site by an adhesive strip **28,** as shown in Figure 4A, or by other means known in the art. In the preferred embodiment, the adhesive strip is constructed of the same vapor permeable polyurethane material as the occlusive drape **16**, having an adhesive coated on one side for securing the strip to the pad **26** and the intact skin surrounding the wound.

[0027] The occlusive wrapping **10** forms a pouch **30** when it is folded along its centerline and the lower edges **31** are bonded together at **33** as shown in Figure 5. In practice, the pouch **30** is placed over the wound and contoured pad 20, as illustrated in Figures 4B and 4C. A fingerhold **36a** is provided to facilitate grasping the pouch 30 and holding it in place as the liner 35 is removed to expose an adhesive backing on layer **16b.** The edges **32a, 32b** of the pouch **30** are brought into contact with the intact skin surrounding the wound by means of an adhesive backing. A removable liner **35** is pulled off, starting at finger tab **35a,** exposing the adhesive, as shown in Figure **4C.** The removable liner **35** may be statically adhered to the adhesive backing to protect the adhesive during handling.

[0028] As illustrated in Figure 4D, a second removable liner **37** is adhered to the receiving **site 20** to protect the adhesive on the wound facing layer **16a** along the receiving **site 20** during handling, and which is removed prior to adhesion of the receiving site **20** to a region **40** of intact skin away from the wound site, so as to prevent dislodgement of the fluid communication port **18** during movement of the patient, as shown in Figure **4E,** A removable, protective liner **36** may be overlaid on the occlusive drape **16,** so as to provide rigidity to the manifold during handling, and which is removed after securing the pouch **30** to the wound site, as shown in Figure 4F.

[0029] A fluid communication port **18** is positioned over the receiving site **20, and** is secured in place also by means of an adhesive contact surface on the communication port **18.** As known in the art of negative pressure wound therapy, a fluid communication means **42,** such as a flexible silicone tube, communicates négative pressure to the wound from a negative pressure source **44**, such as a portable pump. A collection canister **46** is positioned in line between the negative pressure source **44** and the fluid communication means **42** to collect any exudates that may be drawn from the wound.

[0030] While the invention has been described herein with reference to certain preferred embodiments, theses embodiments have been presented by way of example only, and not to limit the scope of the invention, Many other variations are possible, which would be obvious to one skilled in the art. Accordingly, the scope of the invention should be identified only in accordance with the claims that follow.

Claims

1. A wound dressing for use under negative pressure, the wound dressing having a contoured pad adapted for placement in a wound, the wound dressing **characterized by**:

an occlusive wrapping (10) adapted for positioning over the contoured pad, wherein the occlusive wrapping has a receiving site and a wound contact region displaced from the receiving site, and wherein the occlusive wrapping is for allowing negative pressure to be delivered to the receiving site and transported to the wound contact region for application to the wound;
wherein the occlusive wrapping (10) comprises:

an occlusive drape (16) having a wound-facing layer (16a) and an outer layer (16b),
a fluid manifold (14) having a part positioned at the receiving site and a part positioned at the wound contact region, the parts being connected to each other such that negative pressure applied at the part positioned at the receiving site is transported to the part positioned at the wound contact region, wherein the fluid manifold (14) comprises a porous polymer foam material,
wherein the fluid manifold (14) is enclosed within the occlusive drape between the wound-facing layer and the outer layer,
a plurality of fenestrations (19) formed on the occlusive drape (16) at the wound contact region, and
an adhesive on at least an edge of the occlusive drape (16) for sealing the occlusive wrapping (10) to the area surrounding the wound; and

a fluid communication port (18) through at least a layer of the occlusive drape (16) for communicating fluid from the fluid manifold (14) to a source of negative pressure.

2. The wound dressing of claim 1, wherein the occlusive drape (16) is bonded along an edge to form a pouch for receiving an extremity of a patient.

3. The wound dressing of claims 1 or 2, wherein said fluid manifold (14) comprises fluid communicator arms (22) extending at the distal end of the fluid manifold.

4. The wound dressing of claims 3, wherein said communicator arms (22) form contiguous loops.

Patentansprüche

1. Wundverband zur Verwendung unter Unterdruck, wobei der Wundverband ein konturangepasstes Kis-

sen aufweist, das zur Platzierung in einer Wunde ausgelegt ist, und der Wundverband **gekennzeichnet ist durch**:

eine okklusive Umhüllung (10), die zur Positionierung über dem konturangepassten Kissen ausgelegt ist, wobei die okklusive Umhüllung eine Aufnahmestelle und einen von der Aufnahmestelle versetzten Wundkontaktbereich aufweist, und wobei die okklusive Umhüllung dazu dient, zu erlauben, dass Unterdruck an die Aufnahmestelle geleitet und zum Wundkontaktbereich zur Ausübung auf die Wunde befördert wird;
wobei die okklusive Umhüllung (10) umfasst:

ein okklusives Abdecktuch (16), das eine Wundauflageschicht (16a) und eine Außenschicht (16b) aufweist,
einen Fluidschlauchbogen (14), der ein Teil aufweist, das an der Aufnahmestelle positioniert ist, und ein Teil, das am Wundkontaktbereich positioniert ist, wobei die Teile so miteinander verbunden sind, dass Unterdruck, der auf das an der Aufnahmestelle positionierte Teil ausgeübt wird, zu dem am Wundkontaktbereich positionierten Teil befördert wird, wobei der Fluidschlauchbogen (14) ein poröses Polymerschaummaterial umfasst,
wobei der Fluidschlauchbogen (14) in dem okklusiven Abdecktuch zwischen der Wundauflageschicht und der Außenschicht umschlossen ist,
mehrere Befensterungen (19), die auf dem okklusiven Abdecktuch (16) am Wundkontaktbereich ausgebildet sind, und
ein Klebemittel auf zumindest einem Rand des okklusiven Abdecktuchs (16) zum Versiegeln der okklusiven Umhüllung (10) mit dem die Wunde umgebenden Bereich; und

eine Fluidverbindungsöffnung (18) **durch** zumindest eine Schicht des okklusiven Abdecktuchs (16) zum Leiten von Flüssigkeit vom Fluidschlauchbogen (14) zu einer Unterdruckquelle.

2. Wundverband nach Anspruch 1, wobei das okklusive Abdecktuch (16) entlang eines Rands zusammengefügt ist, um einen Beutel zum Aufnehmen einer Extremität des Patienten zu bilden.

3. Wundverband nach Anspruch 1 oder 2, wobei der Fluidschlauchbogen (14) Fluidverbindungsarme (22) umfasst, die sich am distalen Ende des Fluidschlauchbogens erstrecken.

4. Wundverband nach Anspruch 3, wobei die Verbindungsarme (22) zusammenhängende Schleifen bilden.

Revendications

1. Un pansement destiné à être utilisé sous pression négative, le pansement ayant un coussinet profilé adapté pour être placé dans une blessure et **se caractérisant par** ce qui suit :

une enveloppe occlusive (10) adaptée pour être placée sur le coussinet profilé,
l'enveloppe occlusive ayant un site de réception et une région de contact avec la blessure décalée par rapport au site de réception et l'enveloppe occlusive permettant d'appliquer une pression négative sur le site de réception et de la transporter à la région de contact avec la blessure pour l'application sur la blessure ;
dans lequel l'enveloppe occlusive (10) se compose de ce qui suit :

un écran occlusif (16) ayant une couche destinée à se trouver du côté de la blessure (16a) et une couche externe (16b),
un collecteur fluidique (14) ayant une partie positionnée sur le site de réception et une partie positionnée dans la région de contact avec la blessure, les parties étant reliées ensemble de manière à ce que la pression négative appliquée sur la partie positionnée sur le site de réception soit transportée à la partie positionnée dans la région de contact avec la blessure, le collecteur fluidique (14) comportant un matériau poreux en mousse polymère,
dans lequel le collecteur fluidique (14) est enfermé dans l'écran occlusif entre la couche destinée à se trouver du côté de la blessure et la couche externe,
plusieurs fenêtres (19) formées sur l'écran occlusif (16) dans la région de contact avec la blessure, et
un adhésif présent sur au moins un bord de l'écran occlusif (16) permettant de fermer hermétiquement l'enveloppe occlusive (10) sur la zone entourant la blessure ; et un orifice de communication fluidique (18) traversant au moins une couche de l'écran occlusif (16) afin de transmettre le fluide du collecteur fluidique (14) à une source de pression négative.

2. Le pansement de la revendication 1, dans lequel l'écran occlusif (16) est scellé sur un bord pour former une poche destinée à recevoir une extrémité du patient.

3. Le pansement des revendications 1 ou 2, dans lequel le collecteur fluidique (14) comporte des bras de communication fluidique (22) partant à l'extrémité distale du collecteur fluidique.

4. Le pansement de la revendication 3, dans lequel les bras de communication (22) forment des boucles contiguës.

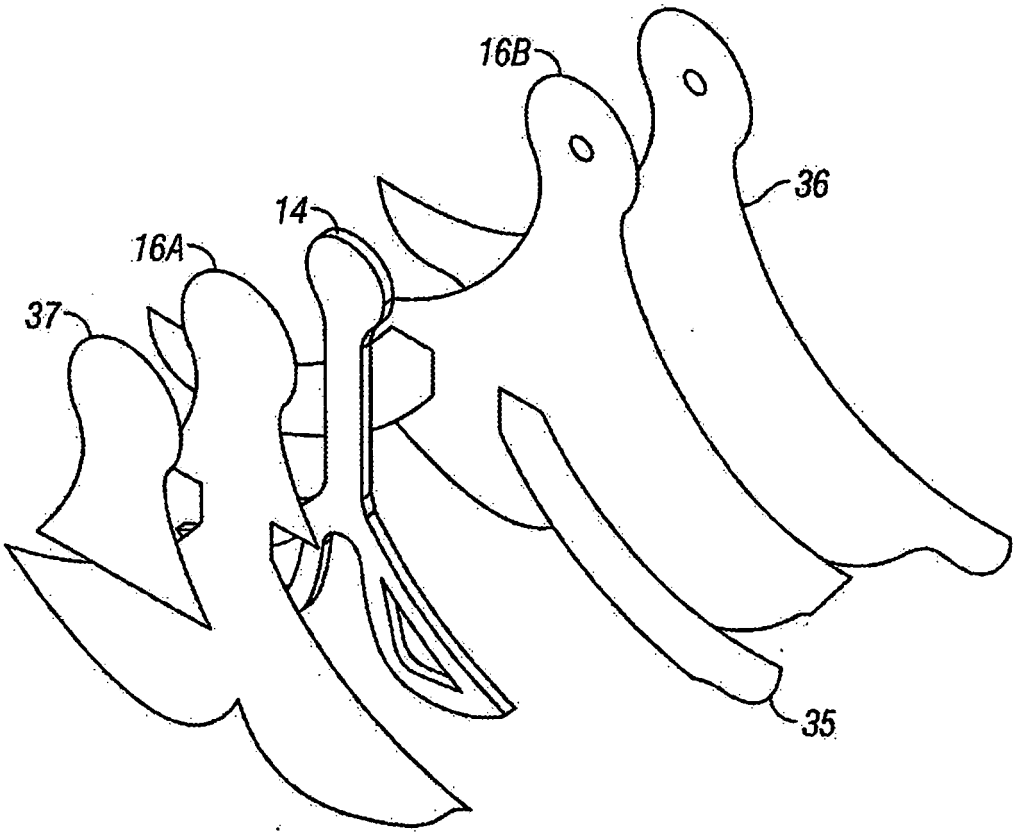


FIG. 1A

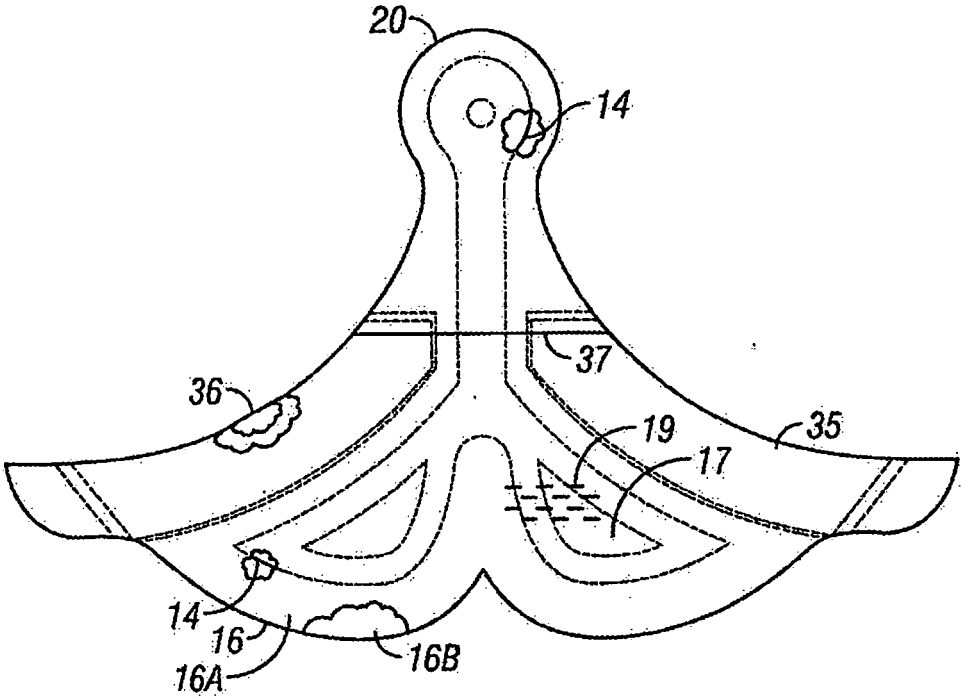


FIG. 1B

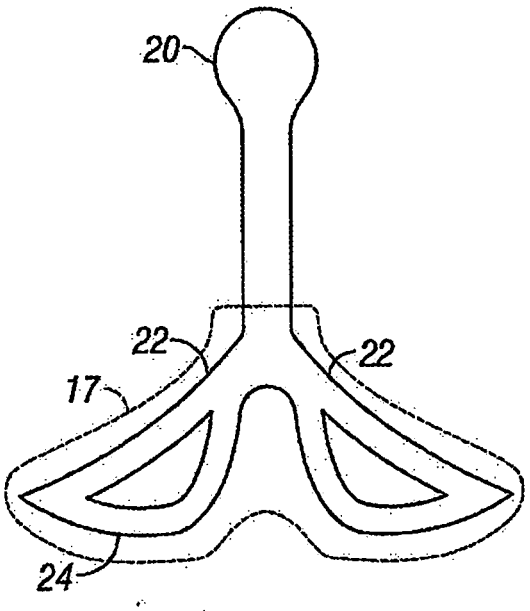


FIG. 2

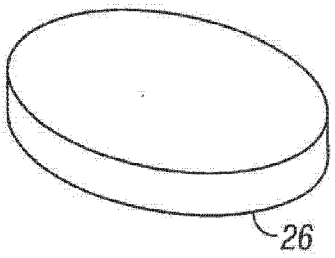


FIG. 3A

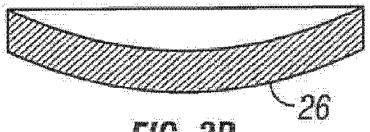


FIG. 3B

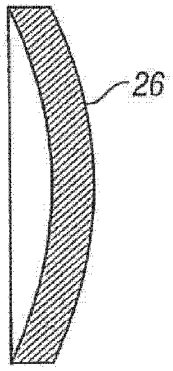


FIG. 3C

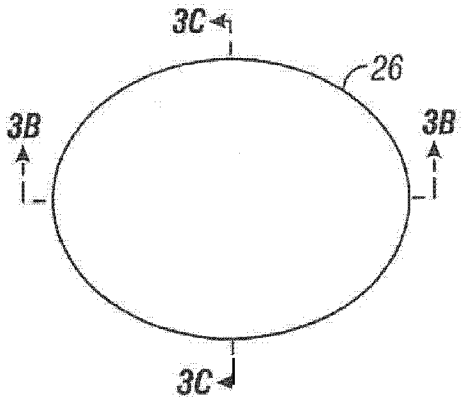


FIG. 3D

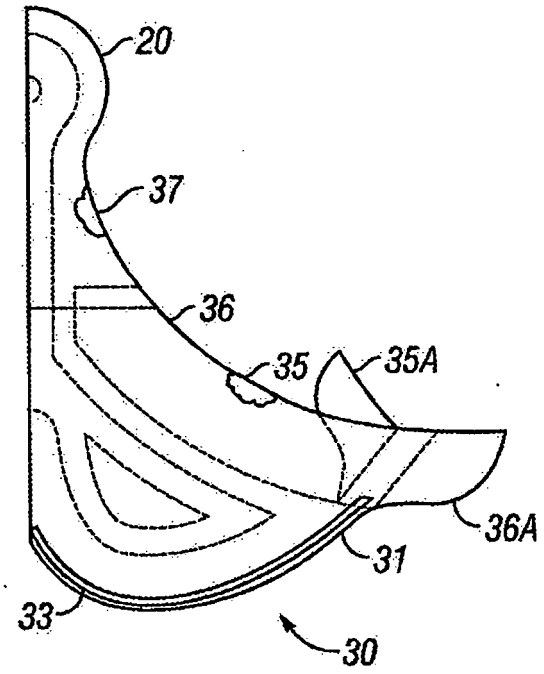


FIG. 5

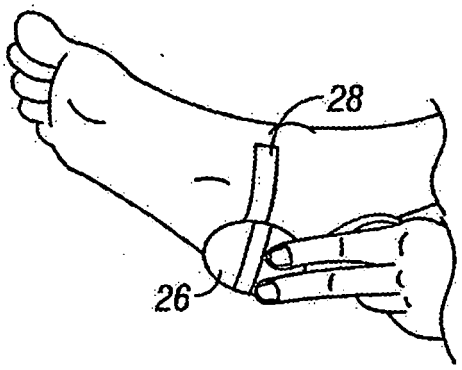


FIG. 4A

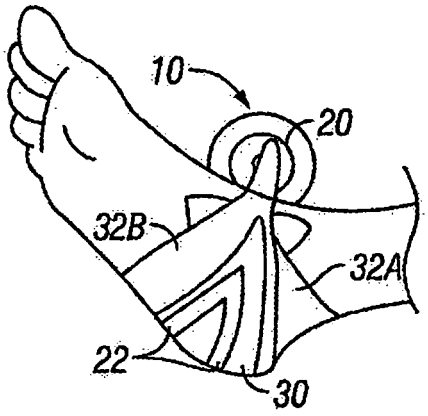


FIG. 4B

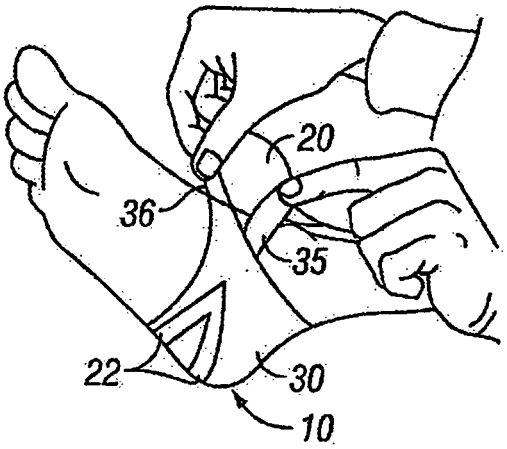


FIG. 4C

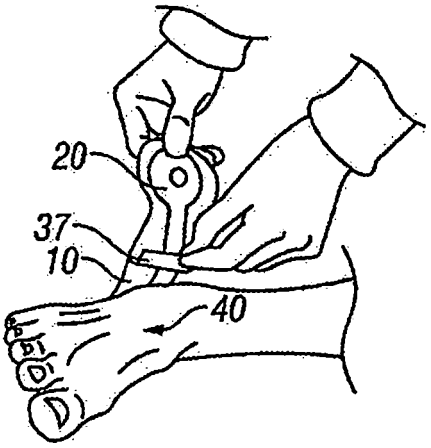


FIG. 4D

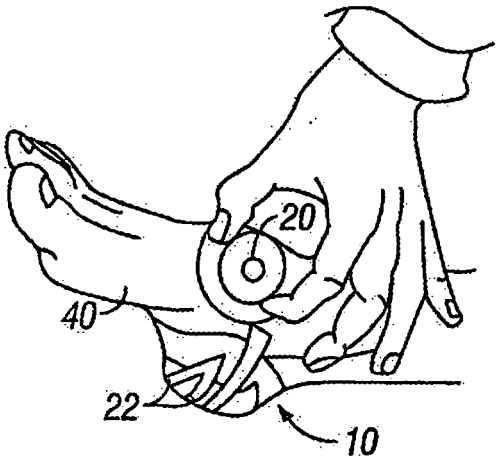


FIG. 4E

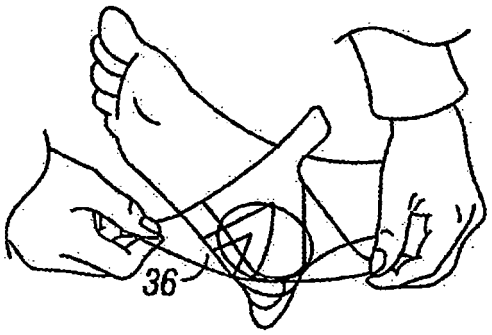


FIG. 4F

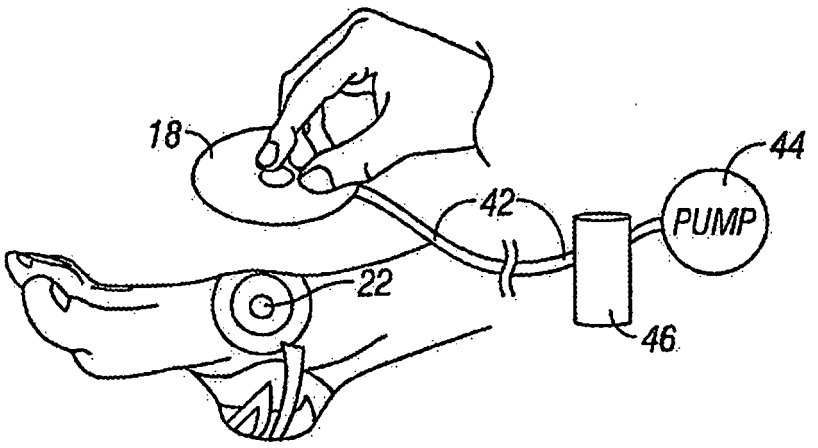


FIG. 4G

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 2001043943 A **[0005]**
- DE 19844355 **[0005]**
- US 2002017304 A **[0005]**
- US 6135116 A **[0005]**
- US 6345623 B **[0010]**